

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

CHARLES JOFFRE BOUCHARD NICKS,
a minor, by his parent and natural guardian,
CRAIG NICKS,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 99-662V

Special Master Christian J. Moran

Filed: October 31, 2007

Hepatitis B; judgment on the record;
autoimmune hemolytic anemia;
failure to establish causation.

*Sheila A. Bjorklund, Lommen Abdo Law Firm, Minneapolis, Minnesota, for petitioner
Nathaniel J. McGovern, United States Dep't of Justice, Washington, D.C. for respondent.*

UNPUBLISHED DECISION ON ENTITLEMENT*

I. Introduction

Craig Nicks, on behalf of his son Charles, filed a petition pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. (1994), for injuries Charles suffered as a result of receiving the hepatitis B vaccination. Mr. Nicks claims that the hepatitis B

* Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

vaccination that Charles received on September 13, 1996, caused Charles to suffer from autoimmune hemolytic anemia (AIHA). Hemolytic anemia is a group of acute or chronic reductions below normal in the concentration of erythrocytes or hemoglobin in the blood, characterized by shortened survival of mature erythrocytes and inability of bone marrow to compensate for the decreased life span. Dorland's Illustrated Medical Dictionary (30th ed. 2003) at 77-78.

Mr. Nicks is pursuing compensation under the theory that Charles suffered an injury that was caused-in-fact by the vaccination. To support his claim, he relies on the medical records. Mr. Nicks also submitted medical literature in support of his position. He did not present any expert testimony specific to his case.

Respondent denies that Charles's injuries were caused by the hepatitis B vaccine. Respondent asserts that the contemporaneous medical records cannot fairly be read to demonstrate that Charles's hemolytic anemia was caused by the vaccine and, instead, contends that the records only show a temporal relationship between the two, which is insufficient to prove causation.

Based on a review of the records, Mr. Nicks has failed to establish that Charles's injuries were caused by his vaccinations. Therefore, he is not entitled to compensation through the Program.

II. Factual Background

Charles was born on December 29, 1989. He was delivered by caesarian section, together with his identical twin brother Aiden, who also seeks compensation in this program. Charles's medical history prior to September 1996, when he received the hepatitis B vaccine, does not

appear to be relevant.

On September 3, 1996, Charles went to the doctor for swelling in his scrotum. He was referred to a urologist. Exhibit 3 at 33. He received his first hepatitis B vaccination on September 13, 1996. Exhibit 1 at 172. Approximately 11 days later, Charles was evaluated by the urologist for a one month history of swelling in the left hemiscrotum. Exhibit 3 at 78. He underwent a hydroceletomy on November 11, 1996. Id. at 91. A hydroceletomy is the excision of a circumscribed collection of fluid. Dorland's at 870.

On December 6, 1996, Charles received his second hepatitis B vaccination. Exhibit 12 at 1. During the next two months, his mother noted that his skin appeared yellow in color. Exhibit 9 (affidavit of Linda Nicks, dated June 27, 2006) at ¶ 6-7. His next visit to the doctor was on March 10, 1997, when Charles was seen by Dr. Malcovic for a 3-day history of coughing. Exhibit 3 at 32. After a series of testing, Charles was found to have a splenomegaly and was diagnosed with cold agglutinin type autoimmune hemolytic anemia (AIHA). Exhibit 3 at 41. A splenomegaly is an enlargement of the spleen. Dorland's at 1741.

Charles was tested for typical causes of AIHA, including parvovirus, cytomegalovirus, myoplasma pneumoniae, and Epstein-Barr virus, and all were negative. Exhibit 4 at 42-48. He also tested negative for antibodies to the hepatitis B virus, despite receipt of the vaccine. Exhibit 3 at 66-67. The only record that offers a cause of his AIHA is from Dr. Roloff who stated

As you are aware patients that have IgM as the cold agglutinin are often related to ... infectious events (mycoplasma or Epstein-Barr virus). In adults this [condition] is often associated with [a] neoplastic process and is monoclonally related to lymphomas. It would appear, though, that Charlie has no evidence of any neoplastic process and he is most likely dealing with an acquired agglutinin secondary to an infectious

event. The fact that we could not identify the particular etiologic agent does not preclude the possibility.

Id. at 88. None of Charles's doctors discuss the hepatitis B vaccination as a possible cause of his anemia, though none rule it out.

Charles has continued to receive treatment for his AIHA and the sequella that he suffered as a result, but none of the subsequent records indicate the cause of his illness and therefore, are not material to the issue of whether the hepatitis B vaccine caused his AIHA.

III. Procedural History

Craig Nicks, Charles's father, filed a petition for compensation on August 5, 1999. No exhibits were filed with his petition. Between 1999 and 2006, the case was stayed pending an attempt between counsel for the multiple petitioners injured by the hepatitis B vaccine and respondent to establish a procedure for resolving claims based on injuries allegedly caused by the hepatitis B vaccine. This attempt was unsuccessful and this case was reassigned to the undersigned on February 8, 2006.

A status conference was held in this case on March 27, 2006, during which the court lifted the stay and ordered Mr. Nicks to file medical records and an affidavit. During 2006 and 2007, petitioner filed 20 exhibits. Four of these exhibits are medical articles upon which Mr. Nicks relies to support his theory of causation. See exhibits 13, 14, 15 and 20.

After most of the medical records were filed, Mr. Nicks was given an opportunity to present an expert report. Order, dated November 22, 2006. However, during the time provided, Mr. Nicks did not submit an expert report. On June 4, 2007, respondent submitted its report, pursuant to Vaccine Rule 4. In this report, respondent denied that petitioner was entitled to

compensation and noted, among other problems, that there was no expert report to support the petition. Respondent's Report at 12-13.

Mr. Nicks was then given another opportunity to obtain an expert report. Order, dated June 8, 2007 (setting deadline as August 17, 2007). Mr. Nicks did not file an expert report within this time. Instead, on August 31, 2007, Mr. Nicks filed a motion for ruling on the record, in which he claimed that he had established that Charles's hemolytic anemia was caused by the hepatitis B vaccination.

Respondent filed a response to the motion on September 17, 2007. Respondent argued that Mr. Nicks had not met the requisite burden of proof to establish that the vaccination caused his injury. This matter is now ripe for a decision.

IV. Discussion

A. Whether A Judgment On The Record Is Appropriate

Mr. Nicks has requested a ruling based upon the record in this case. The records are sufficiently developed that a decision may be made as to whether Mr. Nicks is entitled to a Program award. See 42 U.S.C. § 300aa-12(d)(3)(B)(v); Vaccine Rule 8(b). It appears that Mr. Nicks has exhausted the possibilities of obtaining an expert report. Therefore, continued development of this case is unlikely to be productive. Thus, Mr. Nicks's motion for judgment on the record is GRANTED.

B. Whether Petitioner Is Entitled To Compensation

To receive compensation for his injuries, Mr. Nicks must establish that Charles's AIHA was a consequence of the vaccinations. 42 U.S.C. § 300aa-13(a)(1)(A), 11(c)(1)(C)(ii). Mr. Nicks may meet this standard in either of two ways. First, he can establish that Charles

experienced, within the appropriate time, an injury listed in the Vaccine Injury Table. 42 C.F.R. § 100.3. Alternatively, Mr. Nicks can establish that the vaccines were the cause in fact of his son's AIHA. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). The only injury associated with the hepatitis B vaccine on the vaccine injury table is anaphylaxis, 42 C.F.R. § 100.3 (category VIII), and Mr. Nicks does not claim this injury. Here, Mr. Nicks alleges that the hepatitis B vaccination was the cause in fact of the AIHA.

A petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." 42 U.S.C. § 300aa-13(b)(1)(A). If the medical records do not support a petitioner's claim, a medical opinion must be offered in support. Mr. Nicks has offered no such opinion, therefore this court relies solely on the medical records and the submitted literature to determine whether the vaccination was the cause of his illness.

The Federal Circuit stated the elements a petitioner must establish to be entitled to compensation. The petitioner's

burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec’y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec’y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Mr. Nicks acknowledges the Althen factors and discusses how the facts of his case meet those criteria. Pet’r Mot. at 8-10.

For the first factor of Althen, Mr. Nicks submitted medical articles that, according to Mr. Nicks, support a causal connection between the receipt of the hepatitis B vaccine and AIHA. He also cited cases in which special masters found that vaccines can cause AIHA. For the reasons that follow, the evidence presented by Mr. Nicks does not establish the first factor of Althen and does not support a finding of causation.

The first article is entitled “Vaccine and autoimmune disease: what is the evidence?” Exhibit 13. This article discusses the general mechanisms through which a vaccination can cause an autoimmune disease. The article does not discuss the hepatitis B vaccine or autoimmune hemolytic anemia. Id. Its generality, therefore, does not assist Mr. Nicks.

The second article discusses treatment in a case of AIHA following a diphtheria-pertussis-tetanus (“DPT”) vaccination. Exhibit 14. Again, this article fails to address the specific question. It does not discuss AIHA associated with the hepatitis B vaccination. Without an expert opinion explaining why the hepatitis B vaccine would follow the same analysis as the DPT vaccine, this article is insufficient to establish a relevant medical theory.

The third article is entitled “Immune-mediated hemolytic anemia.” Exhibit 15. This article primarily summarizes the disease of immune-mediated hemolytic anemia, in terms of its diagnoses, treatments and pathology. See generally exhibit 15. The only reference to immunizations is the following: “[t]he Donath-Landsteiner antibody of paroxysmal cold

hemoglobinuria (PCH) ... is most commonly encountered in children as a response to a viral illness or immunization.” Id. at 59. This article may not be relevant because the medical records are inconsistent as to whether Charles tested positive for the Donath-Landsteiner antibody. See exhibit 3 at 88 (a report from April 28, 1997, stating that the antibody “was assayed for and found to be negative”); exhibit 8 at 85 (testing from November 3, 1998, indicating a strong positive); exhibit 7 at 138 (report from June 23, 2000, stating that testing for the antibody was negative).

Even if Charles were assumed to have the antibody, the article is difficult to interpret without guidance from an expert. For example, no expert has explained the relationship between the Donath-Landsteiner antibody and AIHA. Thus, this article holds little persuasive value.

The final article cited is entitled “Vaccine-associated immune hemolytic anemia in two children.” Exhibit 20. In this article, the authors discuss two case reports of hemolytic anemia following a variety of vaccinations, including the hepatitis B vaccination. In their attempt to determine if a vaccination caused AIHA, they cite to cases of vaccine-induced autoimmune thrombocytopenia and a relationship between vaccinations and AIHA in dogs. Id. at 908. The authors discuss the temporal relationship, and but also state “the mechanism by which vaccination may lead to the production of antibodies is largely unknown.” Id.

Nowhere in this article do the authors specifically link the hepatitis B vaccination with AIHA. Rather, the hepatitis B vaccine is named as one of six immunizations received before the onset of AIHA. Id. This article does not reach the conclusion that the hepatitis B vaccination caused AIHA. In fact, the authors state “until now, no specific type of vaccination can be identified as a trigger of abnormal immune responses.” Id. However, the authors do not identify

how or which vaccinations can now be specifically identified as a trigger. Thus, this article (like the preceding articles) does not present a theory explaining how the hepatitis B vaccine can cause AIHA.

Mr. Nicks also cites to two cases in which a special master found, based upon the evidence presented in those cases, that petitioners proved that the vaccines caused AIHA. Brown v. Sec'y of Health and Human Servs., Fed. Cl. No. 99-44V, 2000 WL 1207255 (Fed. Cl. Spec. Mstr., Aug. 3, 2000); Elsperger v. Sec'y of Health and Human Servs., Cl. Ct. No. 90-3850, 1991 WL 255131 (Ct. Cl. Spec. Mstr., November 14, 1991).

Citing these cases does not advance Mr. Nicks's case. Whether a medical theory links an injury to a vaccination is a factual question, dependent upon the evidence introduced in those cases. For the court to reach the same conclusion in Mr. Nicks's case, he must have introduced the evidence from Brown and Elsperger that supported the theory of causation. Allen v. Sec'y of Health & Human Servs., Fed. Cl. No. 99-504V, 2006 WL 2990221 *6 (Fed. Cl. Spec. Mstr., Oct. 4, 2006). However, he did not introduce this evidence. Significantly, the cases cited did not involve the hepatitis B vaccinations. Without a medical expert, there is no basis for applying the findings of Brown or Elsperger or associating a theory of a different vaccine with the hepatitis B vaccine involved in the present case.

Furthermore, even if this evidence had been introduced into this case, the result might have been different because special masters enjoy discretion in how they evaluate evidence and are not bound by the findings of other special masters. Guillory v. Sec'y of Health & Human Servs., 59 Fed. Cl. 121, 124 (2003).

Even if the findings alone from Brown and Elsperger could be separated from their

underlying evidence and imported into this case, Mr. Nicks's case would still lack an essential element of proof. Mr. Nicks has cited no evidence that demonstrates the second factor required by Althen – a logical sequence of cause and effect showing that the vaccination was the reason for the injury.

Mr. Nicks has not identified any statements from treating doctors that support his claim. A review of the record reveals none. Dr. Roloff stated that he was unable to identify any etiologic cause of Charles's AIHA. Exhibit 3 at 88. At no point does Dr. Roloff or any other treating physician associate the hepatitis B vaccine with the disease. Furthermore, Mr. Nicks does not present the opinion of an expert to establish the logical sequence of cause and effect that the vaccination caused Charles's AIHA. Accordingly, he has failed to meet his burden of proving a logical sequence of cause and effect between the hepatitis B vaccination and Charles's injury, under the second prong of Althen.

Finally, Mr. Nicks appears to fulfill the third prong of Althen, the appropriate temporal relationship. Although Mr. Nicks does not have an expert to testify as to what the appropriate temporal relationship should be between the cause of the AIHA and the onset of the disease, several of the articles that he cites support his assertion that one month is an appropriate interval.

Mr. Nicks contends that the temporal relationship is appropriate because autoimmune disorders generally take time to develop. Based on the articles submitted, the time of onset for AIHA following vaccination varies. The earliest time was 5 days and the latest was 6 weeks. Exhibit 14 at 570, table 2; exhibit 20 (case reports showing signs of onset of AIHA 2 weeks and 4 days after vaccination). Charles began looking jaundiced within a month of his vaccination. Exhibit 9 at ¶ 6-7. This time frame falls within what is considered medically appropriate for

onset of AIHA following a vaccination. Thus, Mr. Nicks has established that the temporal relationship between the vaccination and the onset of Charles's condition is appropriate.

"Temporal association is not sufficient, however, to establish causation in fact." Grant v. Sec'y of Health and Human Servs., 956 F.2d 1144, 1148 (Fed. Cir.1992) (citing Hasler v. United States, 718 F.2d 202, 205 (6th Cir.1983)). While Mr. Nicks satisfies the third prong of Althen, he has still failed to satisfy the first two prongs. As discussed above, none of the literature filed indicates a relationship between the hepatitis B vaccine and the development of AIHA. It is not appropriate to draw a connection between the hepatitis B vaccine and an injury simply because that injury has an association with other vaccines. Grace v. Sec'y of Health and Human Servs., No. 04-[redacted], 2006 WL 3499511, *9 (Fed. Cl. Spec. Mstr., Nov. 30, 2006).

None of the literature cites the hepatitis B vaccine as a cause of AIHA. At best, it cites the hepatitis B vaccination as one of six vaccinations received by a child who developed AIHA shortly after immunization. See exhibit 20. Moreover, none of Charles doctors has connected the hepatitis B immunizations with the onset of his AIHA. Consequently, he has failed to meet his burden of proof under Althen and is not entitled to compensation.

V. Conclusion

Judgment cannot be granted in petitioner's favor because he has not met all three of the elements that Althen requires for proving causation in fact. Petitioner's motion for ruling on the record is GRANTED and his claim for compensation is DENIED. Judgment shall enter accordingly.

IT IS SO ORDERED.

S/Christian J. Moran

Christian J. Moran
Special Master